UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

KACEY WILSON,

Plaintiff,

v.

COLOURPOP COSMETICS, LLC,

Defendant.

Case No. 22-cv-05198-TLT

ORDER GRANTING SECOND MOTION TO DISMISS

Re: ECF No. 42

Before the Court is Defendant ColourPop Cosmetics, LLC's ("Defendant") motion to dismiss Plaintiff Kacey Wilson's ("Plaintiff") second amended complaint under Rule 12(b) and Rule 9(b) of the Federal Rules of Civil Procedure. Def.'s Mot. to Dismiss ("Mot."), ECF No. 42. On August 29, 2023, the parties presented oral arguments. *Williams v. ColourPop Cosms., LLC*, No. 22-5198 (N.D. Cal. argued Aug. 29, 2023). Having carefully considered the parties' briefs, oral arguments, the relevant legal authority, and for the reasons below, the Court **GRANTS** Defendant's motion to dismiss without leave to amend.

I. BACKGROUND

Plaintiff is an individual consumer and a resident of San Francisco, California. Second Amendment Class Action Complaint ("Am. Compl.") ¶ 18, ECF No. 41. Defendant is registered as a limited liability company in the State of California and has its principal place of business at 1451 Vanguard Drive, Oxnard, California. *Id.* ¶ 19. Defendant "designs, formulates, manufactures, markets, advertises, distributes, and sells a wide range of consumer cosmetic products including but not limited to, eyeshadow, eyeliner, eyelid primer, and eyebrow pencils, nationwide, including in California." *Id.* Defendant sells its products in retail stores throughout

the United States and on its website. *Id.* ¶¶ 20, 22.

The products at issue in this lawsuit include "eyeshadow palettes (which Defendant sometimes refers to and promotes as, inter alia, 'shadow palettes,' 'pigment palettes,' or 'pressed powder palettes') and eyeliner products that are formulated with and/or contain certain color additives that are not safe for use in the eye area." Am. Compl. ¶ 2 (collectively, the "Products"). According to Plaintiff, the Products contain "color additives and ingredients that are dangerous when used on the immediate eye area." *Id.* ¶ 1. Through its marketing, advertising, public statements, and social media posts and videos, Defendant instructs consumers like Plaintiff to use the Products in the eye area, and "the only reasonable and foreseeable use of the Products is cosmetic application in the eye area." *Id.* ¶ 3. Therefore, Plaintiff argues that Defendant "misrepresents the purpose of the Product and misleads consumers that the Products are intended for use in the eye area when they are unsafe and unfit for use in that manner." *Id.*

Plaintiff claims that the Products are unsafe and unfit for use in the eye area because:

> they are formulated with and/or contain one or more of the following color additives: FD&C Red No. 4; D&C Red No. 6, 7, 17, 21, 22, 27, 28, 30, 31, 33, 34, 36; D&C Violet No. 2; Ext. D&C Violet No. 2; FD&C Yellow No. 6; D&C Yellow No. 7, 8, 10, 11; Ext. D&C Yellow No. 7; D&C Orange No. 4, 5, 10, 11; D&C Green No. 6, 8; FD&C Green No. 3; D&C Brown No. 1; and/or D&C Blue No. 4.

("Harmful Ingredients"). Am. Compl. ¶ 4. The Harmful Ingredients can cause physical injuries, including eye pain, skin irritation, skin tanning, and damage through their toxicity when they enter the body. *Id.* ¶ 5. Plaintiff argues that the presence of one or more of these Harmful Ingredients renders the Products "unsafe and unfit for use in the eye area." *Id.* ¶ 5.

When she purchased the Products, Plaintiff was unaware that they contained these Harmful Ingredients, and she "would not have purchased the Products or would have paid substantially less for the Products" if she would have known. Am. Compl. ¶ 11. Plaintiff further alleges she "reasonably relied on Defendant's representations and omissions when she decided to…use [the Products] . . . in the eye area." Am. Compl. ¶¶ 72, 163, 100. Plaintiff also contends she was not aware of any "warnings, safety issues, or instructions for use indicating that the Products are not safe or fit for use in the eye area" and was not aware of any warnings or disclosures that the

Products contain color additives that are not safe or fit for use in the eye area. *Id.* ¶¶ 73-74.

Plaintiff proposes a nationwide class and a California subclass. Am. Compl. ¶ 80. The nationwide class includes "[a]ll persons residing in the United States who purchased ColourPop Eye Makeup containing Harmful Ingredients during the maximum period permitted by law." *Id.* The California subclass includes "[a]ll members of the Class who purchased ColourPop Eye Makeup containing Harmful Ingredients in California during the maximum period permitted by law." *Id.* Plaintiff filed her second amended complaint on April 27, 2023, and she brings the following seven causes of action: (1) Breach of Implied Warranty, (2) Breach of Implied Warranty Under the Song-Beverly Consumer Warranty Act, Cal. Civil Code §§1790, et seq., (3) Unjust Enrichment or Restitution, (4) False Advertising Law, Cal. Bus. & Prof. C. §17500, et seq. ("FAL"), (5) Consumers Legal Remedies Act, Cal. Civ. Code §1750, et seq. ("CLRA"), (6) Unfair Competition Law, Cal. Bus. & Prof. C. §17200, et seq. ("UCL"), and (7) Fraud.

II. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(1)

Under Rule 12(b)(1), a party may move to dismiss for lack of subject matter jurisdiction. "[L]ack of Article III standing requires dismissal for lack of subject matter jurisdiction under [Rule] 12(b)(1)." *Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th Cir. 2011). The "irreducible constitutional minimum" of standing requires that a plaintiff must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins* ("*Spokeo II*"), 578 U.S. 330, (2016), as revised (May 24, 2016). These three elements are referred to as, respectively, injury-in-fact, causation, and redressability. *Planned Parenthood of Greater Was. & N. Idaho v. U.S. Dep't of Health & Human Servs.*, 946 F.3d 1100, 1108 (9th Cir. 2020). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements," which at the pleadings stage means "clearly . . . alleg[ing] facts demonstrating each element." *Spokeo II*, 578 U.S. 337 (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)).

A Rule 12(b)(1) motion also tests whether a complaint alleges grounds for federal subject matter jurisdiction. A motion to dismiss for lack of subject matter jurisdiction will be granted if

the complaint on its face fails to allege facts sufficient to establish subject matter jurisdiction. *See Savage v. Glendale Union High Sch. Dist. No. 205*, 343 F.3d 1036, 1039 n.2 (9th Cir. 2003).

In considering a Rule 12(b)(1) motion, the Court "is not restricted to the face of the pleadings, but may review any evidence, such as affidavits and testimony, to resolve factual disputes concerning the existence of jurisdiction." *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir. 1988). Once a party has moved to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the opposing party bears the burden of establishing the court's jurisdiction. *See Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1122 (9th Cir. 2010).

B. Federal Rule of Civil Procedure 9(b)

Rule 9(b) heightens the pleading requirements for all claims that "sound in fraud" or are "grounded in fraud." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (citation omitted); Fed. R. Civ. P. 9(b). The Ninth Circuit has interpreted Rule 9(b) to require that allegations of fraud are "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993) (internal quotation marks omitted).

C. Federal Rule of Civil Procedure 12(b)(6)

Under Rule 12(b)(6), a defendant may move to dismiss an action for failure to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted). For purposes of ruling on a Rule 12(b)(6) motion, the Court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008).

Nonetheless, the Court is not required to "'assume the truth of legal conclusions merely

because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). Mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004); *accord Iqbal*, 556 U.S. at 678. Furthermore, "'a plaintiff may plead herself out of court'" if she "plead[s] facts which establish that [s]he cannot prevail on h[er]…claim." *Weisbuch v. Cnty. of L.A.*, 119 F.3d 778, 783 n.1 (9th Cir. 1997) (quoting *Warzon v. Drew*, 60 F.3d 1234, 1239 (7th Cir. 1995)).

III. DISCUSSION

Defendant's motion to dismiss presents several challenges to Plaintiff's second amended complaint, alleging: Plaintiff does not necessarily plead facts sufficient to establish standing, fails to appropriately state a claim, and notwithstanding this, asserts Plaintiff's claims are impliedly preempted by the Food, Drug, and Cosmetic Act. Mot. 2-3. Plaintiff's theory counters these claims as "premature" and instead asserts "this is a straight-forward false and misleading advertising case." Pl.'s Opp'n. to Mot. ("Opp'n.") 1, ECF No. 43. The Court must address jurisdictional issues before reaching the merits of any Rule 12(b)(6) challenges to sufficiency of pleading. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998). Accordingly, the Court begins with standing—discussing the key issue of whether Plaintiff suffered an injury or damage under the asserted claims—and, again, moves to re-evaluate the parties' arguments regarding preemption.

A. Standing

Defendant contests Plaintiff's ability to bring her claims, arguing she lacks an injury-in-fact sufficient to establish Article III standing. Mot. 2. Further, Defendant claims Plaintiff failed to present an adequate injury or damage to plausibly plead her claims in satisfaction of statutory standing or standing for injunctive relief. *Id.* Nevertheless, Defendant asserts Plaintiff's alleged causes of action—or lack thereof—fail to state a claim. *See* Mot. 7, 8, 10, 15, 18, 22-25 (alleging Plaintiff "does not plead injury in fact or damages to support any of her claims").

Plaintiff disagrees. Injury, she says, was the result of Defendant's "material misrepresentations and omissions in marketing and selling the Products." Opp'n 7. Put simply,

Plaintiff alleges her injury stems from "lost money or property as a result of Defendant's conduct . . . and reli[ance] on Defendant's packaging, advertising, representations, and marketing materials when selecting and purchasing ColourPop Eye Makeup." Am. Compl. ¶¶ 92, 107, 123, 142. In diligence to the parties, the Court reviews standing for each asserted cause of action.

1. Article III

"[T]hose who seek to invoke the jurisdiction of the federal courts must satisfy the threshhold requirement imposed by Article III of the Constitution by alleging an actual case or controversy." *City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983). Article III standing requires a plaintiff at an "irreducible minimum" to satisfy three elements: "(1) an injury-in-fact that is (2) fairly traceable to the defendant's allegedly unlawful conduct and that is (3) likely to be redressed by the requested relief." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 590 (1992). Injury rests at the heart of the Court's decision here. To qualify as an injury-in-fact, an alleged harm must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 174 (2000).

a. Injury-in-Fact

Plaintiff says she suffered a concrete injury because "Defendant made material misrepresentations and omissions in marketing and selling the Eye Makeup Products." *See* Am. Compl. ¶¶ 3, 24-28, 59, 126-27. Plaintiff argues these Products contain Harmful Ingredients that render the ColourPop Eye Makeup *unreasonably dangerous* to use in the eye area, to the point that a reasonable consumer "would not purchase the Product[s] at all." Opp'n 10 (emphasis in original). Specifically, at oral argument, Plaintiff asserted that the Product contains forever chemicals and that the disclaimer language does not sufficiently inform consumers of the risks of use.

Defendant mounts Plaintiff's concessions as a defense, explaining that "she used the two [P]roducts" she purchased and repurchased over two years, and those products "did not cause her eye irritation, physical injury, or any other physical symptoms." Mot. 7. Defendant adds that Plaintiff cannot identify "any complaints about a negative physical reaction with the products." Of grave importance, Defendant clarifies that "the FDA has not made a scientific determination

that the additives that are not 'specifically' approved for the eyes are likely to cause injuries." Mot. 8.

"For purposes of ruling on a motion to dismiss for want of standing, both the trial and reviewing courts must accept as true all material allegations of the complaint and must construe the complaint in favor of the complaining party." *Maya*, 658 F.3d at 1068. "In assessing standing, the court may consider 'the complaint and any other particularized allegations of fact in affidavits or in amendments to the complaint.'" *Id.* at 1067 (citing *Table Bluff Reservation (Wiyot Tribe) v. Philip Morris, Inc.*, 256 F.3d 879, 882 (9th Cir. 2001)).

The central question is whether Plaintiff's allegation of injury is based in fact. Plaintiff's injury relies on a determination as to whether the Products purchased are unsafe, or as Plaintiff puts it "unreasonably dangerous" for use in the eye area. Opp'n. 10. As previously discussed, the FDA is responsible for making that determination. *See infra* III.B. Even after removing terms related to Sherman Act or the FDCA, the Court finds that Plaintiff's amended claims ultimately depend on the existence of violations of federal law—the Court can't make a decision the FDA itself did not make. Plaintiff can't have it both ways: Plaintiff either needs the FDCA to identify whether the alleged ingredients in the purchased Products are harmful when applied to the eye area or reference a parallel state law governing the Products in a similar fashion. The Court's hands are tied, and as a result, Plaintiff has not alleged concrete or actual injuries in her use of the Products purchased. Therefore, Plaintiff's allegation that the Products are unsafe is not a fact, but rather, is conclusory in nature.

Further, Plaintiff's allegations that the Products she purchased are unsafe is speculative. The Court can appreciate the possibility of risk of harm if Plaintiff's purchased products are absorbed in the eye at dangerous levels. Still, Plaintiff has neither plausibly alleged that she suffered any injuries the Harmful Ingredients can cause, nor has she shown there is a high probability, or any for that matter, that injury will imminently occur in the future. *Cf. McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 708 (9th Cir. 2020) (explaining that the plaintiff did not allege she underwent medical testing or examination to confirm that she suffers from the conditions caused by her consumption of the harmful product). For example, Plaintiff has not alleged that she

suffered eye irritation or a reaction after using the Products. Nor does she allege that the Harmful Ingredients were not included on the Products' labels.

A validation of Plaintiff's claims—that the purchased makeup is unsafe for use in the eye area—falls squarely out of this Court's jurisdiction, and more importantly, veers too far from Plaintiff's assertions that the Products are unfit for use in the eye area without the appropriate legal authority: none have been provided. Said differently, Plaintiff has not shown that Defendant's conduct—selling makeup to Plaintiff—is illegal. As a result, Plaintiff lacks Article III standing particularly because she cannot establish an injury that plausibly corroborates her assertion that the Products she purchased are "unreasonably dangerous." And without reasonably affirming the products are unsafe, the Court cannot say an actual misrepresentation occurred.

b. Benefit of the Bargain Theory

Moreover, absent physical injury, Plaintiff's claim for economic loss also necessarily relies on establishing the Products she purchased have been deemed unsafe. Though Plaintiff alleges "she spent money on Defendant's Products that she otherwise would not have had she known her Products were unsafe and carried unreasonable risk to use for their sole intended purpose," *see* Am. Compl. ¶¶ 11, 77, 101 118, 128, 144, 177, this "loss of money" requires a showing that the Products are *actually* harmful. "[U]nder the benefit of the bargain theory, a plaintiff might successfully plead an economic injury by alleging that she bargained for a product worth a given value but received a product worth less than that value." *McGee*, 982 F.3d 700 at 705–06 (citations omitted).

Plaintiff relies on *McGee*, asserting "each Product [she] purchased was worthless at the time of sale due to Defect . . . because they contain ingredients unfit and unsafe for use in the eye area that confer a risk of eye irritation and/or damage." Opp'n 9. But as *McGee* clarifies, "[a] plaintiff [] must do more than allege that she 'did not receive the benefit she thought she was obtaining.' [Instead, she] must show that she did not receive a benefit for which she actually bargained." *McGee*, 982 F.3d 700 at 705–06.

It is true, as Plaintiff argues that, in *McGee*, "the plaintiff did not contend that the defendant made any representations about the product's safety." *Id.* at 706. However, this misses

the point. The Ninth Circuit explains, and this Court agrees, that "although the plaintiff may have assumed the product [she purchased] contained only safe and healthy ingredients, her assumptions were not included in the bargain, particularly given the labeling disclosure that the product contained [certain ingredients]." *Id.* Absent those unmet expectations, the court in *McGee* determined that the plaintiff was not "denied the benefit of her bargain" unless she made allegations that defendant "made false representations" about the product's safety. *Id.*

The Court applies the same logic here with a twist. Even if Plaintiff assumed the ColourPop makeup she purchased contained only safe and healthy ingredients, her beliefs too were not included in the bargain. While Plaintiff did make an allegation of false representation, she cannot establish the harm required to convey the Products she purchased were unfit and unsafe. And without a showing of actual harm related to the Products' use, the apparent need for disclosure is a moot proposition. Although Plaintiff's personal expectations of the makeup she purchased are unmet, the Court finds she was not denied the benefit of her bargain.[1]

2. Statutory Standing

Plaintiffs bringing claims under the UCL, the CLRA, and the FAL must satisfy statutory standing requirements. To establish standing under the CLRA and FAL, plaintiffs must show economic injury and "a plaintiff must claim to have relied on an alleged misrepresentation." *Id.* at *3 citing *Kwikset Corp. v. Superior Ct.*, 51 Cal. 4th 310, 322 (2011); *see also Durell v. Sharp Healthcare*, 183 Cal. App. 4th 1350, 1367 (2010)). And to establish standing for a UCL claim, plaintiffs must plead both an injury in fact and that they "ha[ve] lost money or property as a result of the unfair competition," meaning "actual reliance" on the unfair competition "is necessary for standing." *Id.* at *4 (first citing Cal. Bus. & Prof. Code § 17204; then citing *Kwikset Corp.*, 51 Cal. 4th at 326-27; and then citing *In re Tobacco II Cases*, 46 Cal. 4th 298, 306 (2009)).

Defendant argues its "purported failure to disclose information it had no duty to disclose is

[1] Because Plaintiff's benefit-of-the-bargain theory is insufficient, so too is her claim under the overpayment theory. An identifiable, affirmative misrepresentation is the lynchpin of both theories. *See McGee*, 982 F.3d at 707 (rejecting plaintiff's overpayment theory alleging misrepresentation and referencing its benefit-of-the-bargain analysis). Here, the Court similarly concludes that Plaintiff fails to pinpoint any false representation about the Products' safety.

not substantially injurious, immoral, or unethical." Mot. 19. In other words, Defendant contends Plaintiff alleges "no facts about what is unfair about a product she 'used' that works." *Id.* In response, Plaintiff asserts her FAL, CLRA, and UCL claims under the "unfair" and "fraudulent" prongs, fraud claims, and alternative unjust enrichment/restitution claim are all based on Defendant's "marketing and labeling of Products [that was] false or misleading." Opp'n 4. As explained above, Plaintiff has not shown an economic injury or injury-in-fact because her claims are either preempted or unenforceable as currently pleaded. Plaintiff vigorously argues her claims are not preempted and that the Court should only make a factual determination as to whether the Products' labels are false or misleading. Opp'n. 4. The Court finds no misrepresentation occurred because it cannot be said conclusively, statutorily, or absent speculation, that the alleged Harmful Ingredients are unsafe. Thus, Plaintiff lacks statutory standing to bring her asserted claims.

3. Standing to Seek Injunctive Relief

To establish standing for injunctive relief, a plaintiff must plead a "threat of injury" that is "actual and imminent, not conjectural or hypothetical." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009)). Plaintiffs so threatened are entitled to injunctive relief only if they can show that they face a "real or immediate threat that [they] will again be wronged in a similar way." *Mayfield v. United States*, 599 F.3d 964, 970 (9th Cir. 2010). "Where standing is premised entirely on the threat of repeated injury, a plaintiff must show 'a sufficient likelihood that he will again be wronged in a similar way." *City of Los Angeles*, 461 U.S. at 102.

"[A] previously deceived customer may have standing to seek an injunction against false advertising or labeling" based on "inability to rely on the advertising in the future," "even though the consumer now knows or suspects that the advertising was false at the time of the original purchase, because the consumer may suffer an 'actual and imminent, not conjectural or hypothetical' threat of future harm." *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 967 (9th Cir. 2018) (quoting *Summers*, 555 U.S. at 493). "Knowledge that the advertisement or label was false in the past does not equate to knowledge that it will remain false in the future." *Id.*

Plaintiff has not shown she is entitled to injunctive relief. As discussed above, Plaintiff has not established harm or the threat of harm in Defendant's Products. An injury must first exist for

it to be repeated, or said differently, a plaintiff cannot again be wronged when the threat of injury was speculative to begin with. Such is the case here, and accordingly, Plaintiff does not have standing to bring its claims for injunctive relief.

B. Implied Preemption

On April 13, 2023, the Court granted Defendant's motion to dismiss Plaintiff's first amended complaint because Plaintiff's claims were impliedly preempted by the Food, Drug, and Cosmetics Act ("FDCA"). *See* Order Granting Mot. to Dismiss ("Previous Order"), ECF No. 38. As the Court explained in its Previous Order,

> Plaintiff's amended complaint seeks to impose liability on Defendant "*because* [Defendant's] conduct [of allegedly using ingredients designated by the FDA as 'unsuitable and unapproved for cosmetic use in the eye area'] violates the FDCA" and "such claim[s] would be impliedly preempted under *Buckman*." *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (emphasis in original) (quotation omitted). In other words, as presently drafted, Plaintiff's claims allege that the Products are "defective, unsafe, and unsuitable for its intended use" *because* they contain "Harmful Ingredients" designated by the FDA as "unsuitable and unapproved for cosmetic use in the eye area." *See In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1287-92 (C.D. Cal. Dec. 17, 2008) ("As currently pled,…Plaintiffs' allegations of fraud (i.e., deceptive advertising) are so intertwined with allegations that Defendants engaged in [conduct that violates the FDCA] that the Court must dismiss the Complaint in its entirety."). Plaintiff may not use "state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA." *Id.* at 1290-91. Accordingly, Defendant's motion to dismiss based on implied preemption is **GRANTED** with leave to amend**.**

Id. at 7-8.

In its instant motion, Defendant argues that Plaintiff's claims are "still attempting to enforce the FDCA regulations" in violation of *Nexus Pharm., Inc. v. Cent. Admixture Pharm. Servs.*, 48 F.4th 1040 (9th Cir. 2022). Mot. 1. In *Nexus Pharm., Inc.*, the Ninth Circuit held, in part, that "[t]o permit Nexus 'to proceed with a claim that Defendants violated this [FDCA] when the FDA did not so determine would, in effect, permit [Nexus] to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make.'" *Id.* at 1049 (citation omitted). The FDCA "includes a prohibition on private enforcement: all proceedings to enforce or restrain violations of the FDCA must be 'by and in the

name of the United States,' except for certain proceedings by state governments." *Id.* at 1044 (quoting 21 U.S.C. § 337(a)). According to Defendant, Plaintiff's second amended complaint is attempting to plead around implied preemption by "further scrub[ing] her complaint of all references to the FDCA and the FDA in an attempt to avoid dismissal." *Id.*

In response, Plaintiff argues that neither the "FDCA nor the Sherman Act are mentioned or relied on once in the [second amended complaint], with the only exception being one mention of the Sherman Act under the UCL 'Unlawful' prong." Opp'n. 1. In addition, Plaintiff contends that her claims "would be and are valid even if the FDCA never existed" because Plaintiff amended her claims to "specify the serious dangers posed by each of the Harmful Ingredients and clarified her allegations as to Defendant's misrepresentations and omissions." *Id.* As such, Plaintiff argues her claims do not exist solely by virtue of the FDCA requirements, and thus they are not preempted. *Id.*

A plaintiff cannot plead around FDCA preemption if the existence of the claim arises from violation of the FDCA. *See Beckman Co. v. Pl. Legal Comm.*, 531 U.S. 341, 352-53 (2001). Here, Plaintiff alleges that the Products "are inherently dangerous and unfit for use in the eye area *because* they are formulated with and/or contain one or more of the" Harmful Ingredients." Am. Compl. ¶ 4 (emphasis added). Notably, the Harmful Ingredients Plaintiff includes in her second amended complaint are the same Harmful Ingredients she included in her first amended complaint, which Plaintiff previously alleged were ingredients designated by the FDA as unsuitable and unapproved for cosmetic use in the eye area. *Compare* ECF No. 26 at ¶ 3 *with* ECF No. 41 at ¶¶ 3-4. Similarly, Plaintiff alleges that the Products' packaging and descriptions are false and misleading because Defendant's marketing, advertising, public statements, and social media posts and videos instruct consumers like Plaintiff to use the Products in the eye area, yet the Products are "unsafe and unfit for use in that manner." *Id.* ¶ 3.

In sum, although Plaintiff states that she amended her claims to "specify the serious dangers posed by each of the Harmful Ingredients and clarified her allegations as to Defendant's misrepresentations and omissions," her claims still arise from alleged violations of the FDCA. Specifically, the parties agree that the FDA regulates the use of the Harmful Ingredients at issue in

this case. *See* Mot. 3 ("Plaintiff was deliberate in picking these FDA-regulated additives because they are the ones that have not yet been 'specifically' approved by the FDA."); *see also* Opp'n. 2 ("Plaintiff challenges solely the inclusion of Harmful Ingredients that are not approved by the FDA….") (emphasis in original). Thus, the Court's reasoning in its Previous Order dismissing Plaintiff's first amended complaint applies here as Plaintiff alleges that the Products are defective because they contain Harmful Ingredients that are not approved by the FDA for use around the eye area. *See, e.g.*, Am. Compl. ¶¶ 1-4, 6-8, 10, 11, 13, 21-24, 26 ("This is the crux of Defendant's misleading conduct: Defendant sells Products that should not and cannot be used in the eye area yet markets the Products such that their sole reasonable and foreseeable use by consumers is cosmetic application in the eye area."). As such, the Court finds that Plaintiff's claims still "exist solely by virtue of the FDCA…requirements." Previous Order at 7 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)).

"The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with 'its substantive provisions.'" *Buckman Co.*, 531 U.S. at 349 n.4. "As other courts have recognized, 'the [FDCA's] public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA.'" *Somers v. Beiersdorf, Inc.*, 467 F. Supp. 3d 934, 939-40 (S.D. Cal. 2020) (quoting *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013)).

Here, although the Court agrees with Plaintiff that the FDCA is not mentioned once in the second amended complaint, Plaintiff's claims, in substance, nevertheless seek to enforce the FDCA by holding Defendant liable for its alleged use of Harmful Ingredients—which are not approved by the FDA for use in the eye area—in Products for which "the only reasonable and foreseeable use…is cosmetic application in the eye area." *See, e.g.*, Am. Compl. ¶ 3. "The FDA is responsible for investigating potential violations of the FDCA, and the Act provides the agency with a range of enforcement mechanisms, such as injunction proceedings, civil and criminal penalties, and seizure." *Perez*, 711 F.3d at 1119 (citing 21 U.S.C. §§ 332-34, 372). Accordingly, Defendant's motion to dismiss based on implied preemption is **GRANTED.**

C. Leave to Amend

In her opposition, Plaintiff "requests leave to amend to address any deficiencies the Court may identify." Opp'n 25. Under Federal Rule of Civil Procedure 15(a)(2), a party may amend its pleadings with leave of the court. Fed. R. Civ. P. 15(a)(2). Courts "should freely give leave when justice so requires," and this policy is applied with "extreme liberality." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003) (internal citation omitted). The Supreme Court has outlined five factors in considering whether to grant leave to amend: (1) bad faith on the part of the movant, (2) undue delay by the movant, (3) repeated amendments by the movant, (4) undue prejudice to the nonmovant, and (5) futility of the proposed amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962). The nonmovant bears the burden of demonstrating why leave to amend should not be granted. *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 187 (9th Cir. 1987).

Here, the first two factors weigh in favor of granting Plaintiff further leave to amend because there is no indication in the record before the Court that Plaintiff is proceeding in bad faith or that Plaintiff has unduly delayed seeking leave to amend. However, factors two and three weigh against granting Plaintiff further leave to amend. Specifically, the Court notes that this is Plaintiff's second amended complaint and Defendant has now filed three separate motions to dismiss.[2] Thus, the prejudice to Defendant from Plaintiff's further amendment is high since any amendment complaint may require Defendant to file a fourth motion to dismiss.

Nevertheless, although Rule 15's standard is liberal regarding amendment, the Court granted Plaintiff reprieve in amending her complaint on two occasions. Absent a ruling on harm regarding Defendant's Products, the Court hereby **DENIES** Plaintiff the opportunity to amend her complaint. *See Perez*, 711 F.3d at 1120 ("The plaintiff must be suing for conduct that violates the FDCA (or else h[er] claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under

[2] Defendant filed its first motion to dismiss Plaintiff's original on November 11, 2022. *See* ECF No. 20. Instead of filing an opposition to Defendant's first motion to dismiss, Plaintiff filed an amended complaint as a matter of course pursuant to Federal Rule of Civil Procedure 15(a)(1). *See* Fed. R. Civ. P. 15(a)(1). On December 8, 2022, the Court denied Defendant's first motion to dismiss as moot without prejudice since an "amended complaint supersedes the original, the latter being treated thereafter as non-existent." ECF No. 27 (quoting *Ramirez v. Cnty. of San Bernardino*, 806 F.3d 1002, 1008 (9th Cir. 2015)).

Buckman).") (emphasis in original) (citation omitted).

IV. CONCLUSION

Plaintiff lacks subject matter jurisdiction, and Plaintiff's claims as pleaded are impliedly preempted. Thus, for the above reasons, Defendant's motion to dismiss is **GRANTED** without leave to amend. Accordingly, the Court declines to reach the Rule 9 failure to state a claim argument.

This Order terminates docket number 42.[3]

IT IS SO ORDERED.

Dated: September 6, 2023

TRINA L. THOMPSON
United States District Judge

[3] Because the Court finds Plaintiff's claims are impliedly preempted, it need not reach the question of whether Plaintiff's claims are subject to dismissal under Rule 12(b)(6) and Rule 9(b). *See Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 778 (2000) ("Questions of jurisdiction, of course, should be given priority—since if there is no jurisdiction there is no authority to sit in judgment of anything else.") (citation omitted). In addition, because the Court did not consider any information contained in Defendant's requests for judicial notice, the Court **DENIES** Defendant's request for judicial notice as moot. RJN, Ex. 1-3, ECF No. 42-1.